SEP 2 0 2007

Docket No.: V0179.70001US00

(PATENT)

N THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Erich Wanker et al.

Serial No.:

09/485,005

Confirmation No.:

1379

Filed:

September 11, 2000

For:

METHOD OF DETECTING AMYLOID-LIKE FIBRILS OR

PROTEIN AGGREGATES

Examiner:

G. Gabel

Art Unit:

1641

Certificate of Mailing Under 37 CFR 1.8(a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: September 17, 2007

TRANSMITTAL LETTER

Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed are the following items for filing in connection with the above-referenced Patent Application:

- 1. Renewed Petition To Withdraw Holding Of Abandonment Under 37 CFR §1.181(a)
- 2. Copy of Dismissed Petition
- 3. Copy of Paperwork Mailed August 2, 2007 (Petition To Withdraw Holding Of Abandonment Under 37 CFR §1.181(a); Application Data Sheet; Copy of Postcard with OIPE date stamp of May 4, 2007; Copy of Notice of Abandonment; Copy of Mailing from May 1, 2007 including Postcard, Check, Transmittal, Response to Office Action, Petition for 2-Month Extension of Time, and Fee Transmittal)

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 23/2825, under Docket No.

V0179.70001US00. A duplicate copy of this paper is enclosed.

Dated: September 17, 2007

Respectfully submitted,

MaryDilys S. Anderson, Ph.D.

Registration No.: 52,560

WOLF, GREENFIELD & SACKS, P.C.

Federal Reserve Plaza 600 Atlantic Avenue

Boston, Massachusetts 02210-2206

(617) 646-8000

Wolf, Greenfield & Sacks, P.C.

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450

HELEN C LOCKHAR

SEP 1 2 2007

WOLF GREENFIELD & SACKScketed in

A!ready Docketed

FEDERAL RESERVE PLAZANot Required Initials 1st **600 ATLANTIC AVENUE** BOSTON MA 02210-2211

HCL

COPY MAILED

SEP 1 0 2007

OFFICE OF PETITIONS

In re Application of Erich Wanker et al.

Application No. 09/485,005 Filed: September 11, 2000

Attorney Docket No. V0179/7001

ON PETITION

This is a decision on the petition filed August 6, 2007 under 37 CFR 1.181 to withdraw the holding of abandonment of the above-identified application.

The petition is **DISMISSED**.

Any request for reconsideration of this decision must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Renewed Petition under 37 CFR 1.181," or, as explained in more detail below, "...under 37 CFR 1.137(a)" or (b). This is not a final agency decision.

The above-referenced application was held abandoned on March 13, 2007, for failure to file a timely response to the non-Final Office Action mailed December 11, 2006, which set a three (3)-month statutory period for reply. Accordingly, a Notice of Abandonment was mailed July 24, 2007.

Petitioner contends that a response to the December 11, 2006 non-Final Office Action was timely filed on May 1, 2007 and points to copies of the response with a certificate of mail dated May 1, 2007 and a postcard receipt date stamped on May 4, 2007 by the USPTO. Unfortunately, neither has been located with the instant petition.

Perhaps the papers were included with the petition and became separated but until such time as sufficient proof of a timely response (including any appropriate extensions of time previously filed) having been filed, the holding of abandonment will not be withdrawn and the notice of abandonment will not be vacated.

Further correspondence with respect to this matter should be addressed as follows:

By mail:

Mail Stop Petition

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

By FAX:

(571) 273-8300

Telephone inquiries concerning this matter may be directed to the undersigned Petitions Attorney at (571) 272-3212.

Patricia Faison-Ball

Senior Petitions Attorney

Office of Petitions



Docket No.: V0179.70001US00

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Erich Wanker et al.

Serial No.:

09/485,005

Confirmation No.:

1379

Filed:

September 11, 2000

For:

METHOD OF DETECTING AMYLOID-LIKE FIBRILS OR

PROTEIN AGGREGATES

Examiner:

G. Gabel

Art Unit:

1641

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I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: September 17, 2007

RENEWED PETITION TO WITHDRAW HOLDING OF ABANDONMENT UNDER 37 C.F.R. § 1.181(a)

Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Applicants file this Renewed Petition To Withdraw Holding Of Abandonment Under 37 C.F.R. § 1.181(a) in response to the Dismissed Petition Mailed September 10, 2007.

The Petition to withdraw the holding of abandonment of the above-identified application was dismissed based because the copies of the response with a certificate of mail dated May 1, 2007, and a postcard receipt date stamped on May 4, 2007 by the USPTO were not associated with the file by the USPTO. Applicants have included herewith copies of the response with a certificate of mailing dated May 1, 2007 and the postcard receipt date stamped May 4, 2007 to replace those missing from the file. Applicant hereby files a renewed petition the Commissioner to withdraw the holding of abandonment under 37 CFR § 1.181(a) for the above-identified application for patent. A copy of the Notice of Abandonment and the USPTO decision dismissing the petition are enclosed.

As set forth in the petition under 37 CFR § 1.181(a) to withdraw the holding of abandonment of the above-identified application, an Office Action was received from the USPTO on December 11, 2006. A response to that Office Action was mailed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 1, 2007. The May 1, 2007 response was accompanied by a proper certificate of mailing.

The U.S. Patent and Trademark Office received Applicants' May 1, 2007 communication, as evidenced by the date-stamped return receipt postcard, but the communication appears not to have been entered into the file. Accordingly, the application went abandoned. A copy of the response to the December 11, 2006 Office Action, which was originally mailed to the U.S. Patent and Trademark Office on May 1, 2007, is enclosed herewith. Additionally, enclosed is a copy of the return receipt postcard sent to the U.S. Patent and Trademark Office with the amendment mailed May 1, 2007 and stamped by OIPE on May 4, 2007. Applicants accordingly believe that the papers filed on May 1, 2007 to the U.S. Patent and Trademark Office constituted a timely and complete response to the last pending Office Action.

Applicants do not believe that this petition requires a fee [(see MPEP 711.03(c) (I)], as Applicants timely filed the response, and thus did not abandon this application. Accordingly, no such fee is included. In the event that a fee is due, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 23/2825, under Docket No. V0179.70001US00. A duplicate copy of this paper is enclosed.

Dated: September 17, 2007

Respectfully submitted,

By SA. Anderson, Ph.D.

Registration No.: 52,560

WOLF, GREENFIELD & SACKS, P.C.

Federal Reserve Plaza 600 Atlantic Avenue

Boston, Massachusetts 02210-2206

(617) 646-8000



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Atty Docket No.: V0179.70001US00

WGS Date: 08/24/07

Inventor:

Erich Wanker et al.

Filing Date: September 11, 2000

Application No.: 09/485,005

METHOD OF DETECTING AMYLOID-LIKE FIBRILS OR PROTEIN

AGGREGATES

The USPTO Mail Room acknowledges receipt of the following on the date stamped hereon:

Transmittal Letter

Petition To Withdraw Holding Of Abandonment Under 37 CFR § 1.181(a)

Application Data Sheet

Via: First Class Mail - Certificate of Mailing Under 37 CFR 1.8(a)

Sender's initials: MXA/mlb

Date Mailed: August 2, 2007



Docket No.: V0179.70001US00

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Erich Wanker et al.

Serial No.:

09/485,005

Confirmation No.:

1379

Filed:

September 11, 2000

For:

METHOD OF DETECTING AMYLOID-LIKE FIBRILS OR

PROTEIN AGGREGATES

Examiner:

G. Gabel

Art Unit:

1641

Certificate of Mailing Under 37 CFR 1.8(a)

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Dated: August 2, 2007

Melissa L.B. Lyons

TRANSMITTAL LETTER

Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed are the following items for filing in connection with the above-referenced Patent Application:

- 1. Petition To Withdraw Holding Of Abandonment Under 37 CFR §1.181(a); and
- 2. Application Data Sheet.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 23/2825, under Docket No.

V0179.70001US00. A duplicate copy of this paper is enclosed.

Dated: August 2, 2007

Respectfully submitted,

MaryDilys S. Anderson, Ph.D.

Registration No.: 52,560

WOLF, GREENFIELD & SACKS, P.C.

Federal Reserve Plaza 600 Atlantic Avenue

Boston, Massachusetts 02210-2206

(617) 646-8000



Docket No.: V0179.70001US00

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Erich Wanker et al.

Serial No.:

09/485,005

Confirmation No.:

1379

Filed:

September 11, 2000

For:

METHOD OF DETECTING AMYLOID-LIKE FIBRILS OR

PROTEIN AGGREGATES

Examiner:

G. Gabel

Art Unit:

1641

Certificate of Mailing Under 37 CFR 1.8(a)

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Dated: August 2, 2007

Melissa L.B. Lyons

PETITION TO WITHDRAW HOLDING OF ABANDONMENT UNDER 37 C.F.R. § 1.181(a)

Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The above-identified application became abandoned based on failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. Applicant hereby petitions the Commissioner to withdraw the holding of abandonment under 37 CFR § 1.181(a) for the above-identified application for patent. A copy of the Notice of Abandonment is enclosed.

The last communication received from the U.S. Patent and Trademark Office in this application was mailed on December 11, 2006. A response to that Office Action was mailed to the

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 1, 2007. The May 1, 2007 response was accompanied by a proper certificate of mailing.

The U.S. Patent and Trademark Office received applicant's May 1, 2007 communication, as evidenced by the date-stamped return receipt postcard, but the communication appears not to have been entered into the file. Accordingly, the application went abandoned. A copy of the response to the December 11, 2006 Office Action, which was originally mailed to the U.S. Patent and Trademark Office on May 1, 2007, is enclosed herewith. Additionally, enclosed is a copy of the return receipt postcard sent to the U.S. Patent and Trademark Office with the amendment mailed May 1, 2007 and stamped by OIPE on May 4, 2007. Applicants accordingly believe that the papers filed on May 1, 2007 to the U.S. Patent and Trademark Office constituted a timely and complete response to the last pending Office Action.

Applicants do not believe that this petition requires a fee [(see MPEP 711.03(c) (I)], as Applicants timely filed the response, and thus did not abandon this application. Accordingly, no such fee is included. In the event that a fee is due, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 23/2825, under Docket No. V0179.70001US00. A duplicate copy of this paper is enclosed.

Dated: August 2, 2007

Respectfully submitted,

MaryDilys S. Anderson, Ph.D.

Registration No.: 52,560

WOLF, GREENFIELD & SACKS, P.C.

Federal Reserve Plaza 600 Atlantic Avenue

Boston, Massachusetts 02210-2206

(617) 646-8000

SEP 20 200 Application Data Sheet

Application Information

Application Type:: Regular

Subject Matter:: Utility

Suggested Group Art Unit:: 1641

CD-ROM or CD-R?:: None

Sequence submission?:: None

Computer Readable Form (CRF)?:: No

Title:: METHOD OF DETECTING AMYLOID-LIKE

FIBRILS OR PROTEIN AGGREGATES

Attorney Docket Number:: V0179.70001US00

Request for Early Publication?:: No

Request for Non-Publication?:: No

Small Entity?:: Yes

Petition included?:: No

Secrecy Order in Parent Appl.?:: No

Applicant Information

Applicant Authority Type:: Inventor

Primary Citizenship Country:: Austria

Status:: Full Capacity

Given Name:: Erich

Family Name:: Wanker

City of Residence:: Berlin

Country of Residence:: Germany

Street of mailing address:: Leichhardtstrasse 61

City of mailing address:: Berlin

Country of mailing address:: Germany

Postal or Zip Code of mailing address:: D-14195

Applicant Authority Type:: Inventor

Primary Citizenship Country:: Austria

Status:: Full Capacity

Given Name:: Hans

Family Name:: Lehrach

City of Residence:: Berlin

Country of Residence:: Germany

Street of mailing address:: Terrassenstr 31

City of mailing address:: Berlin

Country of mailing address:: Germany

Postal or Zip Code of mailing address:: D-14129

Applicant Authority Type:: Inventor

Primary Citizenship Country:: Germany

Status:: Full Capacity

Given Name:: Eberhard

Family Name:: Scherzinger

City of Residence:: Berlin

Country of Residence:: Germany

Street of mailing address:: Lützelsteiner Weg 52

City of mailing address:: Berlin

Country of mailing address:: Germany

Postal or Zip Code of mailing address:: D-14195

Applicant Authority Type:: Inventor

Primary Citizenship Country:: United Kingdom

Status:: Full Capacity

Given Name:: Gillian

Family Name:: Bates

City of Residence:: London

Country of Residence:: United Kingdom

Street of mailing address:: Flat 2, 8 St. Martin's Close

City of mailing address:: London

Country of mailing address:: United Kingdom

Postal or Zip Code of mailing address:: NW1 0HR

Correspondence Information

Correspondence Customer Number:: 23628

Main Phone Number:: (617) 646-8000

Direct Dial Practitioner Phone Number:: (617) 646-8301

Fax Number: (617) 646-8646

Patent Practitioner E-Mail Address:: manderson@wolfgreenfield.com

Representative Information

Representative Customer Number:: 23628

Domestic Priority Information

Foreign Priority Information

Country::	Application Number::	Filing Date::	Priority Claimed::
		MM/DD/YY	
	PCT/EP98/04810	07/31/1998	Yes
EP	97113320.2	08/01/1997	Yes

Assignee Information

Assignee Name:: MAX-PLANCK-GESELLSCHAFT ZUR

FÖRDERUNG DER WISSENSCHAFTEN E.V.

Street of Mailing Address::

City of Mailing Address:: Berlin

Country of Mailing Address:: Germany

Postal or Zip Code of Mailing Address::

T.O.F.	A	· · · · · · · · · · · · · · · · · · ·	
10 1 F 40	Application No.	Applicant(s)	
Notice of Abandonment	09/485,005	WANKER ET A	L.
SEP 2.0 1981 Notice of Abandonment	Examiner	Art Unit	
\$	Gailene R. Gabel	1641	
The MAILING DATE of this communication ap	opears on the cover sheet with the c	orrespondence ac	ddress
This application is abandoned in view of:			
Applicant's failure to timely file a proper reply to the Offi (a) A reply was received on (with a Certificate of period for reply (including a total extension of time or	f Mailing or Transmission dated f month(s)) which expired on), which is after the	·
(b) A proposed reply was received on, but it doe			the final rejection.
(A proper reply under 37 CFR 1.113 to a final rejecti application in condition for allowance; (2) a timely file Continued Examination (RCE) in compliance with 37	ed Notice of Appeal (with appeal fee); of CFR 1.114).	or (3) a timely filed I	Request for
(c) A reply was received on but it does not const final rejection. See 37 CFR 1.85(a) and 1.111. (See	itute a proper reply, or a bona fide atte e explanation in box 7 below).	mpt at a proper rep	oly, to the non-
(d) 🖾 No reply has been received.			
2. Applicant's failure to timely pay the required issue fee a from the mailing date of the Notice of Allowance (PTOL-	-85).		
(a) The issue fee and publication fee, if applicable, was), which is after the expiration of the statutory Allowance (PTOL-85).	period for payment of the issue fee (an		
(b) The submitted fee of \$ is insufficient. A balance			
The issue fee required by 37 CFR 1.18 is \$	·	CFR 1.18(d), is \$	·
(c) The issue fee and publication fee, if applicable, has i	not been received.		
3. Applicant's failure to timely file corrected drawings as red Allowability (PTO-37).			
(a) Proposed corrected drawings were received on after the expiration of the period for reply.	(with a Certificate of Mailing or Tran	smission dated), which is
(b) No corrected drawings have been received.			
The letter of express abandonment which is signed by the applicants.	he attorney or agent of record, the assi	ignee of the entire i	interest, or all of
5. The letter of express abandonment which is signed by a 1.34(a)) upon the filing of a continuing application.	in attorney or agent (acting in a represe	entative capacity ur	nder 37 CFR
6. The decision by the Board of Patent Appeals and Interferon of the decision has expired and there are no allowed cla		e the period for see	sking court review
7. The reason(s) below:			\wedge
		Solo	1/18/2007
		, O. H D. O. H.	4 '

Gailene R. Gabel Primary Examiner Art Unit: 1641

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

U.S. Patent and Trademark Office
PTOL-1432 (Rev. 04-01)

Notice of Abandonment

Part of Paper No. 20070718



Atty Docket No.: V0179.70001US00

WGS Date: May 11, 2007

Inventor: Erich Wanker et al.

Filing Date: January 31, 2000

Application No.: 09/485,005-Conf. #1379

METHOD OF DETECTING AMYLOID-LIKE FIBRILS OR PROTEIN

AGGREGATES

The USPTO Mail Room acknowledges receipt of the following on the date stamped hereon:

Fee Transmittal (1 page)

Two-Month Request for Extension of Time Under 37 CFR 1.136(a) (1 page)

Amendment in Response to Non-Final Office Action (11 pages)

Transmittal Letter (1 page)

Check in the amount of \$225.00



First Class Mail - Certificate of Mailing Under 37 CFR 1.8(a)

Sender's Initials: MXA/sfg

Date Mailed: May 1, 2007

1182282 1



Atty Docket No.: V0179.70001US00

WGS Date: May 11, 2007

Inventor: Erich Wanker et al.

Filing Date: January 31, 2000

Application No.: 09/485,005-Conf. #1379

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Sender's Initials: MXA/sfg

Date Mailed: May 1,2007

1182282 1



DOCKET NO.: V0179.70001US00

HE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Erich Wanker et al.

Serial No.:

09/485,005

Confirmation No.:

1379

Filed:

January 31, 2000

For:

METHOD OF DETECTING AMYLOID-LIKE FIBRILS OR

PROTEIN AGGREGATES

Examiner:

G. Gabel

Art Unit:

1641

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

MaryDilys S. Anderson, Ph.D., Reg. No.: 52,560

MAIL STOP AMENDMENT

Commissioner For Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Response to Office Action (11 pages)
- Petition for 2-Month Extension of Time (1 page)
- Fee Transmittal (1 page)
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check in the amount of \$225.00 is enclosed to cover the filing fee. If the fee is insufficient, the balance may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted, Erich Wanker et al., Applicants

By:

MaryDilys S. Anderson, Ph.D., Reg. No.: 52,560

Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No.: V0179.70001US00

Date: May 1, 2007

x5/11/2007x

PTO/SB/17 (02-07) Approved for use through 02/28/2007. OMB 0651-0032

	Complete if Known
The required to t	espond to a collection of information unless it displays a valid OMB control number
Under the Paperwork Reduction Act of 1995, no person are required to	U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCI respond to a collection of information unless it displays a valid OMB control number

	Effective on 12/08/2004.
s pursuant to the	Consolidated Appropriations Act, 2005 (H.R. 4818).
FEE	TRANSMITTAL

For FY 2007

SEP 2 0 2007

Applicant claims small entity status. See 37 CFR 1.27 TOTAL AMOUNT OF PAYMENT (\$) 225.00

spond to a collection of infor	mation unless it displays a valid OMB control numbe
	omplete if Known
Application Number	09/485,005-Conf. #1379
Filing Date	January 31, 2000
First Named Inventor	Erich Wanker
Examiner Name	G. Gabel
Art Unit	1641
Attorney Docket No.	V0179.70001US00

METHOD OF PAYMEN	T (check all t	hat apply)						
X Check Credit C	ard N	Aoney Order	None	Other (please identif	ỳ):		
Deposit Account Depo	sit Account Numb	per: 23/2825	Deposit Account	Name:	Wolf, G	reenfield & S	acks, P.C.	
For the above-ident	ified deposit	account, the D	irector is he	reby authorize				
Charge fee(s)						ated below, e		ne filina fee
Charge any action (dditional fee(s	s) or underpay and 1.17	ments of		any overpay		·	Ū
FEE CALCULATION			· · · · · · · · · · · · · · · · · · ·					· · · · · · · · · · · · · · · · · · ·
1. BASIC FILING, SEARCH			ES					
		G FEES	SEAR	CH FEES		TION FEES		
Application Type	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fees P	aid (\$)
Utility	300	150	500	250	200	100	10001	GIG IVI
Design	200	100	100	50	130	65		
Plant	200	100	300	150	160	80		
Reissue	300	150	500	250	600	300		
Provisional	200	100	0	0	0	0		
2. EXCESS CLAIM FEES							5	Small Entity
<u>Fee Description</u> Each claim over 20 (includi	ng Reissues)						Fee (\$) 50	Fee (\$) 25
Each independent claim over							200	100
Multiple dependent claims							360	180
Total Claims Extra C	claims F	ee (\$)	Fee Paid	(\$)	<u>Mult</u>	iple Depende	nt Claims	
• =	x	=			Fee		ee Paid (\$)	!
HP = highest number of total clair								-
Indep. Claims Extra C	Claims Fo	99 (\$)	Fee Paid	(\$)				
HP = highest number of Independ		for, if greater than	n 3.					
3. APPLICATION SIZE FEE If the specification and dra listings under 37 CFR 1 sheets or fraction thereo	wings exceed .52(e)), the a	1 100 sheets o pplication siz S.C. 41(a)(1)(f paper (exc e fee due is (G) and 37 (\$250 (\$125 fo CFR 1.16(s).	or small enti	sequence or	computer Iditional 50	
	tra Sheets		f each additi	onal 50 or fract	ion thereof	Fee (\$)	Fee P	aid (\$)
- 100 =		/50	(rou	nd up to a whole	e number) x		·	
 OTHER FEE(S) Non-English Specification 	n \$120 for	(no small a=4	ltu diesees	`			Fees F	Paid (\$)
Other (e.g., late filing sur					oond mart	L	200	
SUBMITTED BY		CE EXIGUISION	i ioi respoi	ise within se	CONG MIONE	<u> </u>	225	5.00

SUBMITTED BY			-			_
Signature		Registration No. (Attorney/Agent)	52,560	Telephone	(617) 646-8000	_
Name (Print/Type)	MaryDilys S. Anderson, Ph.D.			Date	May 1, 2007	-
						_

Certificate of Mailing Under 37 CFR 1.8(a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated:	May 1	2007	

(MaryDilys S. Anderson, Ph.D.)

PTO/SB/22 (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PESTION FOR EXTENSION OF TIME UNDER FY 2006 (Fees pursuant to the Consolidated Appropriations Act	Docket Number (Optional) V0179.70001US00			
Application Number 09/485,005-Conf	Filed Ja	anuary 31,	2000	
For METHOD OF DETECTING AMYLOID-LIKE	FIBRILS OR PROTE	EIN AGGREGATES		
Art Unit 1641		Examiner	G. Ga	bel
This is a request under the provisions of 37 CFR 1.1 identified application. The requested extension and fee are as follows (che			-	
One month (37 CFR 1.17(a)(1))	<u>Fee</u> \$120	Small Entity Fee \$60	\$	
x Two months (37 CFR 1.17(a)(2))	\$450	\$225	\$	225.00
Three months (37 CFR 1.17(a)(3))	\$1020	\$510	\$	
Four months (37 CFR 1.17(a)(4))	\$1590	\$795	\$	
Five months (37 CFR 1.17(a)(5))	\$2160	\$1080	\$	
The Director has already been authorized to a The Director is hereby authorized to charge a Deposit Account Number 23/2825 I am the applicant/inventor. assignee of record of the entire	any fees which may t	pe required, or credit sed a duplicate copy	t any over	payment, to
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NOTE: Signatures of all the inventors or assignees of record of the than one signature is required, see below.	entire interest or their repres	·		
Total of 1 forms are subn	nitted.			
Certificate of M	lalling Under 37 CFR 1.8	(a)		

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: May 1, 2007

(MaryDilys S. Anderson, Ph.D.)

SEP 20 2001 BY

DOCKET NO.: V0179.70001US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Erich Wanker et al.

Serial No.:

09/485,005

Confirmation No.:

1379

Filed:

September 11, 2000

For:

METHOD OF DETECTING AMYLOID-LIKE FIBRILS OR

PROTEIN AGGREGATES

Examiner:

Gailene Gabel

Art Unit:

1641

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 1st day of May, 2007.

MaryDilys S. Anderson, Ph.D.

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

AMENDMENT

Sir:

In response to the Office Action mailed December 11, 2006, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this amendment.

Remarks begin on page 7 of this amendment.

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In the Claims

Please replace all prior versions, and listings, of claims in the application with the following list of claims:

- 1. (Previously Presented) A method of detecting the presence of detergent- or ureainsoluble amyloid-like fibrils or protein aggregates in a sample on a filter comprising the following steps:
- (a) contacting a filter with a low capacity for protein adsorption, wherein the filter is cellulose acetate or nitrocellulose, with material of a sample suspected to comprise said amyloid-like fibrils or aggregates which has been previously treated with detergent or urea to solubilize the sample and filtering said sample through the filter to capture said detergent or urea insoluble amyloid-like fibrils or protein aggregates; and
 - (b) detecting whether said amyloid-like fibrils or aggregates are retained on said filter.
- 2. (Original) The method of claim 1 wherein said amyloid-like fibrils or protein aggregates are indicative of a disease.
- 3. (Original) The method of claim 2 wherein said disease is a human disease.
- 4. (Previously Presented) The method of claim 2 wherein said disease is associated with a polyglutamine expansion.
- 5. (Currently Amended) The method of any one of claims 2 to 3 wherein said disease is Huntington's disease; spinal and bulbar muscular atrophy; dentarorubral pallidoluysian atrophy; spinocerebellar ataxia type-1, -2, -3, -6 or -7; Alzheimer disease; bovine spongiform encephalopathy (BSE); primary systemic amyloidosis; secondary systemic amyloidosis; senile systemic amyloidosis; familial amyloid polyneuropathy I; hereditary cerebral amyloid angiopathy; hemodialysis-related amyloidosis; familial amyloid polyneuropathy III; Finnish hereditary systemic amyloidosis; type II diabetes; medullary carcinoma of the thyroid; spongiform encephalopathies: Kuru, Gerstmann-Sträussler-Scheinker syndrome (GSS), familial

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insomnia, <u>and</u> scrapie; atrial amyloidosis; hereditary non-neuropathic systemic amyloidosis; injection-localized amyloidosis; hereditary renal amyloidosis; or Parkinson's disease.

6-7. (Cancelled).

- 8. (Previously Presented) The method of any one of claims 1 to 3 wherein, prior to step (b), the following step is carried out: (b') washing said filter so as to remove detergent- or ureasoluble material of the sample.
- 9. (Previously Presented) The method of any one of claims 1 to 3 wherein detergent- or urea-soluble material of the sample is simultaneously with or subsequent to the contacting of said filter with material of the sample in step (a), sucked through said filter.
- 10. (Previously Presented) The method of any one of claims 1 to 3 wherein detection in step (b) is effected by an antibody, or peptide or polypeptide, preferably a tag or an enzyme, or a fragment or derivative thereof or a chemical reagent that specifically binds to said fibrils or aggregates.
- 11. (Previously Presented) The method of any one of claims 1 to 3 wherein detection in step (b) is performed by electron microscopy, electron scanning microscopy, fluorescence and/or chemiluminescence.
- 12. (Previously Presented) The method of claim 1 wherein said material of the sample is derived from tissues or cells of bacteria, yeast, fungi, plants, insects or animals.
- 13. (Previously Presented) A method of detecting the presence of detergent- or ureainsoluble amyloid-like fibrils or protein aggregates in a sample on a filter comprising the following steps:
- (a) contacting a filter with material of a sample suspected to comprise said amyloid-like fibrils or aggregates which has been previously treated with detergent or urea to solubilize the sample and filtering said sample through the filter to capture said

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detergent or urea-insoluble amyloid-like fibrils or protein aggregates; and

(b) detecting whether said amyloid-like fibrils or aggregates are retained on said filter wherein said material of the sample comprises a fusion protein comprising a peptide or polypeptide that enhances solubility or prevents aggregation of said fusion protein, an amyloidogenic peptide or polypeptide and a cleavable site that separates the above-mentioned components of the fusion protein, the method further comprising the following steps prior to step (a):

- (a') incubating said fusion protein in the presence of a suspected inhibitor of amyloidlike fibril or protein aggregate formation; and
- (a") simultaneously with or after step (a'), further incubating with a compound that induces cleavage at said cleavage site.
- 14. (Original) The method of claim 13 wherein said cleavable site is an enzymatically cleavable site or a chemically cleavable site or a site cleavable by intein self-cleavage in the presence of thiols.
- 15. (Previously Presented) The method of claim 13 further comprising, prior to step (b) and after step (a"):
 - (a") incubation with an inhibitor of said compound that induces cleavage.
- 16. (Previously Presented) The method of claim 13 wherein said amyloidogenic peptide or polypeptide comprises a polyglutamine expansion.
- 17. (Previously Presented) The method of one of claims 4 and 16 wherein said polyglutamine expansion comprises at least 35 glutamines.
- 18. (Previously Presented) The method of any one of claims 1 and 13 wherein said contacting is effected by dotting, spotting or pipetting said material of the sample onto said filter.
- 19. (Previously Presented) The method of any one of claims 1 and 13 wherein said filter is a filter membrane.

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20. (Previously Presented) The method of any one of claims 1 and 13 wherein said detergent is Sodium Dodecyl Sulphate (SDS) or t-octylphenoxypolyethoxyethanol (TRITON X-100TM).

21-26. (Cancelled)

- 27. (Previously Presented) The method of claim 12 wherein said tissues or cells are from mammals, humans, a transgenic animal or a transgenic plant.
- 28. (Previously Presented) The method of one of claims 4 and 16 wherein said polyglutamine expansion comprises at least 41 glutamines.
- 29. (Previously Presented) The method of one of claims 4 and 16 wherein said polyglutamine expansion comprises at least 48 glutamines.
- 30. (Previously Presented) The method of one of claims 4 and 16 wherein said polyglutamine expansion comprises at least 51 glutamines.
- 31. (Previously Presented) The method of claim 13, wherein the compound is an enzyme.
- 32. (Previously Presented) The method of claim 31, wherein the enzyme is a protease.
- 33. (Previously Presented) The method of claim 13 wherein said amyloid-like fibrils or protein aggregates are indicative of a disease.
- 34. (Previously Presented) The method of claim 33 wherein said disease is a human disease.
- 35. (Previously Presented) The method of claim 33 wherein said disease is associated with a polyglutamine expansion.
- 36. (Currently Amended) The method of claim 33 wherein said disease is Huntington's disease; spinal and bulbar muscular atrophy; dentarorubral pallidoluysian atrophy;

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spinocerebellar ataxia type-1, -2, -3, -6 or -7; Alzheimer disease; bovine spongiform encephalopathy (BSE); primary systemic amyloidosis; secondary systemic amyloidosis; senile systemic amyloidosis; familial amyloid polyneuropathy I; hereditary cerebral amyloid angiopathy; hemodialysis-related amyloidosis; familial amyloid polyneuropathy III; Finnish hereditary systemic amyloidosis; type II diabetes; medullary carcinoma of the thyroid; spongiform encephalopathies: Kuru, Gerstmann-Sträussler-Scheinker syndrome (GSS), familial insomnia, and scrapie; atrial amyloidosis; hereditary non-neuropathic systemic amyloidosis; injection-localized amyloidosis; hereditary renal amyloidosis; or Parkinson's disease.

- 37. (Previously Presented) The method of claim 13 wherein said filter with low protein adsorption is cellulose acetate.
- 38. (Previously Presented) The method of claim 13 wherein, prior to step (b), the following step is carried out: (b') washing said filter so as to remove detergent- or urea-soluble material of the sample.
- 39. (Previously Presented) The method of claim 13 wherein detergent- or urea-soluble material of the sample is simultaneously with or subsequent to the contacting of said filter with material of the sample in step (a), sucked through said filter.
- 40. (Previously Presented) The method of claim 13 wherein detection in step (b) is effected by an antibody, or peptide or polypeptide, preferably a tag or an enzyme, or a fragment or derivative thereof or a chemical reagent that specifically binds to said fibrils or aggregates.
- 41. (Previously Presented) The method of claim 13 wherein detection in step (b) is performed by electron microscopy, electron scanning microscopy, fluorescence and/or chemiluminescence.

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REMARKS

Applicants respectfully request reconsideration. Claims 1-5, 8-20 and 27-41 were previously pending in this application. Claims 5 and 36 have been amended to replace commas with semicolons to clarify that the spongiform encephalopathies listed in the claim include Kuru, Gerstmann-Sträussler-Scheinker syndrome (GSS), familial insomnia, and scrapie. As a result, claims 1-5, 8-20 and 27-41 are pending for examination with claims 1 and 13 being independent claims. No new matter has been added.

Allowable Subject Matter

Claims 13-16 and 31-41 have been allowed.

Rejections Under 35 U.S.C. §103

The Examiner rejected claims 1, 10, 12, and 18-20 under 35 U.S.C. §103(a) as being unpatentable over Notario et al., Archivio per le scienze mediche, 135(1):1-8 (1878 Jan-Mar) [Abstract] in view of Mueller (U.S. Patent No. 4,094,775) or Gokcen (U.S. Patent No. 6,428,785). Applicants respectfully traverse the rejection.

To support a *prima facie* case for obviousness, the Examiner must demonstrate motivation to combine the teachings in the references to make the claimed invention, a reasonable likelihood of success in making the combination of references, and that the references teach every element of the claimed invention. Applicants submit that these requirements for a *prima facie* case of obviousness have not been met.

Applicants respectfully submit that the modification of Notario in view of Mueller or Gokcen does not result in the instant invention and that the teaching of the references cannot be combined to make the invention as claimed. Notario, the primary reference relied upon by the Examiner, teaches use of cellulose acetate in electrophoretic protein separation. Mueller and Gokcen both describe use of cellulose acetate to filter proteins. The Notario reference teaches a distinct use of a cellulose acetate membrane and a distinct manner of using a cellulose acetate membranes in the Mueller and Gokcen references.

Applicants submit that the manner of using cellulose acetate membrane for electrophoretic separation as taught in the primary reference, Notario, cannot be modified in light

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of the filtration methods of Mueller or Gokcen to make the instant invention, without significant changes in the method of operation of the cellulose acetate membrane method taught in Notario. As stated in the MPEP "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." MPEP 2143.01(VI) citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Thus, the combination of the teaching of Notario with that of Mueller or Gokcen is not a proper basis for the rejection.

Although electrophoresis and filtration can each be performed with a cellulose acetate membrane, the manner in which a membrane is used in electrophoresis and the manner of its use in filtration are very different. In electrophoresis, a sample is applied at one end of a membrane, and due to an applied electric current, protein components of the sample are separated from each other as they migrate longitudinally along the membrane. The electrophoresed sample does not pass through the membrane but remains in the membrane and the sample components are separated along the membrane by the current - resulting in a pattern of proteins along the membrane. The purpose of the electrophoretic separation on the cellulose acetate membrane is to separate individual protein components on the basis of their electrical change and to permit detection of the resulting longitudinal pattern of separated sample proteins on the membrane. In contrast, in filtration, a sample is applied to a top surface of a membrane and components of the sample that are not retained by the membrane are washed or sucked from the top surface, through the membrane, and out through the bottom surface of the membrane. Unlike the electrophoretic separation method, no electric current is applied and there is no separation of proteins in the sample along the membrane and no resulting longitudinal pattern of separated proteins.

Applicants submit that the use of cellulose acetate as an electrophoretic membrane material as taught by Notario could not be modified by the teaching of Mueller or Gokcen to make the instant filtration-requiring invention without significant changes in the manner in which cellulose acetate membrane of Notario is used. Modification of the teaching of Notario to make the instant invention would change the operation of the cellulose acetate membrane from an electrophoretic surface to a filter that separates urea-soluble from urea-insoluble proteins, which Applicants submit is a significant, and patentably distinct, difference. The necessary modifications would "require a substantial reconstruction and redesign of the elements shown in

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[primary reference] as well as a change in the basic principles under which the [primary reference] construction was designed to operate." *In re Ratti*, at 813, USPQ at 352. Thus, the combination of Notario in view of Mueller or Gokcen does not provide a basis for a *prima facie* case for obviousness.

In addition, the Examiner has not indicated specific motivation for one skilled in the art to combine the electrophoretic methods of Notario with the teaching of Mueller or Gokcen to make the instantly claimed invention. As stated in the MPEP, "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP 2143.01(VI), citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Applicants submit that modification of the electrophoretic use of cellulose acetate disclosed in Notario, to a filtration use of cellulose acetate of the instant invention, would make the modified Notario method unsatisfactory for its intended purpose.

Notario's purpose for using a cellulose acetate membrane electrophoresis is to separate individual proteins of a sample from each other along the membrane – e.g., to generate an electrophoretic pattern of the sample proteins along the membrane, thus allowing identification of the sample proteins based on their migration pattern. Use of a filtration method of the instant invention to separate proteins in a sample separates urea-insoluble from urea-soluble proteins, but does not separate sample proteins from each into a separation pattern along a membrane. The cellulose acetate electrophoretic method of Notario, modified as suggested by the Examiner, would not be suitable for its intended purpose as set forth in the Notario et al abstract. Thus, there is no motivation to combine the references in the manner suggested by the Examiner to modify the teaching of Notario to make the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 10, 12, and 18-20 under 35 U.S.C. §103(a) as being unpatentable over Notario et al. in view of Mueller or Gokcen.

The Examiner rejected claims 2-5, 8, 9, 11, 17, and 27-30 under 35 U.S.C. §103(a) as being unpatentable over Notario et al., Archivio per le scienze mediche, 135(1):1-8 (1878 Jan-Mar) [Abstract] in view of Mueller (U.S. Patent No. 4,094,775) or Gokcen (U.S. Patent No 6,428,785), as applied to claims 1, 10, 12, and 18-20 above, and in further view of Kalchman et al. (WO 97/18825). Applicants respectfully traverse the rejection.

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Applicants submit that the modification of Notario in view of Mueller or Gokcen in further view of Kalchman does not result in the instant invention and that the teaching of the references cannot be combined to make the invention as claimed. As described above, the technology of Notario includes the use of cellulose acetate in electrophoretic separation methods and the technologies in Mueller and Gokcen include the use of cellulose acetate as filters. The technology disclosed in Kalchman relates to the separation of HIP1 and huntingtin proteins by electrophoresis followed by blotting of proteins onto PVDF membranes. Applicants submit that the manner of using cellulose acetate membrane for electrophoretic separation as taught in the primary reference, Notario, cannot be modified in light of the filtration methods of Mueller or Gokcen, in further view of the blotting methods of Kalchman to make the instant invention, without significant changes in the method of operation of the cellulose acetate membrane method taught in Notario. As stated in the MPEP, "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." MPEP 2143.01(VI) citing In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Thus, the combination of the teaching of Notario with that of Mueller or Gokcen, in further view of Kalchman is not a proper basis for an obviousness rejection.

Applicants submit that methods of using cellulose acetate as an electrophoretic membrane material as taught by Notario could not be modified by the teaching of Mueller or Gokcen in view of Kalchman to make the instant filtration-requiring invention without significant changes in the manner in which cellulose acetate membrane of Notario is used. The necessary modifications would "change the principle of operation of the prior invention being modified." Id. Thus, the combination of Notario in view of Mueller or Gokcen does not provide a basis for a *prima facie* case for obviousness.

In addition, the Examiner has not indicted specific motivation for one to combine the electrophoretic methods of Notario with the teaching of Mueller or Gokcen, in further view of Kalchman, to make the instantly claimed invention. As stated in the MPEP, "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP 2143.01(VI), citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). As described above, Applicants submit that modification of the electrophoretic use of cellulose acetate in

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Notario, to a filtration use of cellulose acetate, would make the modified method unsatisfactory for its intended purpose. Notario's purpose for using a cellulose acetate membranes is to electrophoretically separate individual proteins of a sample from each other along the membrane – e.g., to generate an electrophoretic pattern of the sample proteins along the membrane. Use of a filtration method of the instant invention to separate proteins in a sample separates ureainsoluble from urea-soluble proteins, but does not separate sample proteins from each other into a separation pattern along a membrane. Thus, the cellulose acetate electrophoretic method of Notario, modified as suggested by the Examiner, would not be suitable for its intended purpose as set forth in the Notario et al abstract. Thus, there is no motivation to combine the references in the manner suggested and to modify the teaching of Notario to make the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 2-5, 8, 9, 11, 17, and 27-30 under 35 U.S.C. §103(a) as being unpatentable over Notario et al., Archivio per le scienze mediche, 135(1):1-8 (1878 Jan-Mar) [Abstract] in view of Mueller (U.S. Patent No. 4,094,775) or Gokcen (U.S. Patent No 6,428,785), as applied to claims 1, 10, 12, and 18-20 above, and in further view of Kalchman et al. (WO 97/18825).

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted, Erich Wanker et al., Applicant(s)

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Docket No.: V0179.70001US00

Date: May 1, 2007

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